

A COMPARATIVE STUDY OF POSTOPERATIVE ANALGESIA USING INTRATHECAL FENTANYL WITH 0.75% HYPERBARIC ROPIVACAINE AND INTRATHECAL FENTANYL WITH 0.5% HYPERBARIC BUPIVACAINE FOR LOWER LIMB SURGERIES

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Received : 29/08/2023
Received in revised form : 22/09/2023
Accepted : 05/10/2023

Keywords:

Analgesia, Ropivacaine, Bupivacaine, Fentanyl.

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DOI: 10.47009/jamp.2023.5.6.84

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5 (6); 400-404



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Abstract

Background: Subarachnoid block is the most commonly used regional anaesthesia. Bupivacaine is being extensively used for S.A block as it produces adequate sensory and motor blockade. Ropivacaine has advantages like early motor recovery and hemodynamic stability. Intrathecal opioids are synergistic action with local anaesthetics and intensify the sensory block without increasing the sympathetic blockade. **Materials and Methods:** This study was conducted in 30 patients of ASA physical status 1 and 2 undergoing lower limb procedures at Owaisi Hospital and Research Center, after obtaining approval from ethical committee and written informed consent from all the patients included in the study. This study was done in a prospective randomized controlled method. Patients were randomly allocated into two groups. Each group consists of 15 patients. Group B- Patients in this group received spinal anaesthesia with 0.5% hyperbaric Bupivacaine 2 ml with Fentanyl 20mcg. Group R- Patients in this group received spinal anaesthesia with 0.75% hyperbaric Ropivacaine 2 ml with Fentanyl 20mcg. **Result: & Conclusion:** In our study to compare the postoperative analgesia using intrathecal 0.75 % hyperbaric Ropivacaine with Fentanyl and intrathecal 0.5% hyperbaric Bupivacaine with Fentanyl, we conclude that 0.75 % hyperbaric Ropivacaine provides early recovery of sensory and motor blockade for lower limb surgeries with stable haemodynamic.

INTRODUCTION

Subarachnoid block is the most commonly used regional anaesthesia technique in contemporary anaesthesia practice. Motor block from subarachnoid block beyond the duration of surgery is undesirable as it prevents early ambulation and urinary retention. Selection of rapid, short acting local anaesthetic agents minimize the adverse effects of anaesthesia on the recovery process.

Bupivacaine is being extensively used for subarachnoid block as it produces adequate sensory and motor blockade. However, it has its own disadvantages such as prolonged motor blockade and cardiac toxicity.

But Ropivacaine has its own advantages such as early motor recovery and hemodynamic stability.

Intrathecal opioids are synergistic action with local anaesthetics an intensify the sensory block without increasing the sympathetic blockade. One such opioid commonly used is Fentanyl which acts on mu receptors thereby intensifies sensory blockade.

MATERIALS AND METHODS

After getting approval from ethical committee and written informed consent from all the patients included in the study. The study was done in a prospective randomized controlled method in 30 patients. Patients were randomly allocated into two groups. Each group consists of 15 patients. This study was conducted in adult patients of age group 30-65 years in ASA I and II physical status, after informed

consent. Patients underwent surgeries like orthopaedic surgeries, lower limb cellulitis etc. All the patients were assessed clinically preoperatively and presence of any medical disorder and history of drug intake was ruled out. Patient with h/o angina/palpitations/syncope, h/o respiratory problems, hepatic or renal problems were excluded from the study. ECG abnormalities were excluded from the study. All the patients underwent the routine investigations. Patients were randomly allocated into two groups (n=15 each) using a computer generated randomization chart.

Group B

Patients in this group received spinal anaesthesia with 0.5% hyperbaric Bupivacaine 2 ml with Fentanyl 20mcg.

Group R

Patients in this group received spinal anaesthesia with 0.75% hyperbaric Ropivacaine 2 ml with Fentanyl 20mcg.

Patients who satisfied the inclusion criteria were explained about the nature of the study and the anaesthetic procedure and written informed valid consent was obtained from the patients. All the patients who were included in the study were reviewed one day prior to surgery. Patients were kept nil by mouth for 6 hours prior to the procedure. Prior to surgery in the premedication room, vital signs of the patient were recorded. An 18 G intravenous cannula secured and preloaded with Ringer Lactate before subarachnoid block.

In the operation room all equipments including appropriate equipment for airway management and emergency drugs were kept ready. Then the patient was shifted into the operating room and made lie on the operating table after confirming the horizontal position of the table. Standard monitors were connected and baseline blood pressure, pulse rate, respiratory rate and oxygen saturation were recorded. Then the subarachnoid block was performed.

The patients were asked to sit straight and under aseptic precautions, a midline lumbar puncture was done in the L3-L4 space using 25 G Quincke needle and after confirming CSF flow by aspiration, drug was injected into the subarachnoid space. Patient is then placed in supine position. The time at which intrathecal injection given was taken as zero time and the following parameters were recorded

heart rate,

1. systolic blood pressure
2. diastolic blood pressure
3. mean arterial pressure
4. Peak block height
5. Onset of sensory and motor blockade
6. Time to Peak block height
7. Time for two segment regression
8. Time to motor blockade Bromage 3
9. Rescue Analgesia

After completion of surgery patient were shifted to the recovery room where the vital signs were recorded for 6 hours. After complete resolution of motor blockade, patients shifted to postoperative ward. At the end of surgery, the degree of pain was assessed using numeric scoring system. Pain assessment was done every hourly for 6 hours. Rescue analgesia with Inj.Diclofenac sodium 2 mg / kg i.m. was given when the patient complaints of pain or numeric scoring was 4 or more. Patients were monitored in the postoperative period for the side effects like headache, paraesthesia in the lower limbs, low back pain, nausea, vomiting and shivering.

RESULTS

The age distribution of study subjects in both groups were similar and only minor difference was observed. [Table 1]

Table 1: Age distribution of the study sample (n=30)

Characteristics	Group Ropivacaine (N=15)		Group Bupivacaine (N=15)		P Value
	n	%	n	%	
Age group (years)	36 to 40	5	25	5	0.651
	41 to 45	5	25	5	
	46 to 50	5	25	7	
	51 to 55	1	5	2	
	Above 50	4	20	1	

Table 2: Comparison of blockade characteristics of the study sample (n=30)

Characteristics	Group Ropivacaine (N=15)		Group Bupivacaine (N=15)		P value
	Mean	SD	Mean	SD	
Onset of sensory and motor blockade (min)	5.4	2.1	4.9	2.2	0.426
Time to Peak block height(min)	8.9	2.7	8.7	3.1	0.870
Time for two Segments regression (min)	78.5	7.6	78.0	7.8	0.839
Time for regression to L1(min)	145.0	11.4	152.0	16.1	0.054
Time for complete regression S2(min)	140.8	14.7	198.0	22.1	0.000
Time to motor blockade Bromage 3 (min)	7.4	1.7	6.0	2.4	0.039
Time to Bromage 0 (min)	130.8	10.8	183.8	12.8	0.000
Rescue analgesia (min)	148.7	9.2	183.4	6.6	0.000

The minor differences in the onset of sensory and motor blockade, time to Peak block height, time for two segments regression, time for regression and time for complete regression between the groups were not statistically significant ($p>0.05$) and hence both the groups were comparable with regards to the above said parameters.

Table 3: Comparison of mean heart rate of the study groups at various perioperative time points (n=30)

Peri-operative Heart Rate	Group Ropivacaine (N=15)		Group Bupivacaine (N=15)		P value
	Mean HR (/min)	SD	Mean HR (/min)	SD	
0 min	76.6	8.8	79.2	7.8	0.329
15 min	72.2	8.6	73.6	5.4	0.527
30 min	71.5	8.1	71.5	5.5	0.982
45 min	70.9	6.9	70.3	4.9	0.753
90 min	71.7	6.2	71.9	6.0	0.918
120 min	72.4	5.9	72.5	6.1	0.958

There was no statistically significant difference between the mean heart rate between the 2 groups throughout the peri-operative period as suggested by the student "t" test.

Table 4: Comparison of mean systolic blood pressure (SBP) of the study groups at various peri-operative time points (n=30)

Peri-operative Systolic Blood pressure	Group Ropivacaine (N=15)		Group Bupivacaine (N=15)		P value
	Mean SBP (mm Hg)	SD	Mean SBP (mm Hg)	SD	
0 min	123.4	11.0	124.7	10.1	0.710
15 min	112.6	7.7	110.5	4.5	0.299
30 min	115.2	7.6	111.3	5.7	0.074
45 min	118.5	6.9	113.4	4.5	0.009
60 min	119.1	6.8	115.3	25.4	0.523
90 min	120.8	7.3	122.1	6.2	0.546
120 min	121.2	7.5	111.5	5.1	<0.001

There was a statistically significant difference in mean SBP between 2 groups throughout at several time points in the peri-operative period though there was more difference noted with subjects in Bupivacaine group experiencing lesser systolic blood pressure than subjects in the Ropivacaine group as suggested by the student t test. (p value<0.001).

Table 5: Comparison of mean diastolic blood pressure (DBP) of the study groups at various per-operative time points (n=30)

Peri-operative diastolic Blood pressure	Group Bupivacaine (N=15)		Group Ropivacaine (N=15)		P value
	Mean DBP (mm Hg)	SD	Mean DBP (mm Hg)	SD	
0 min	73.6	6.7	82.6	7.6	0.000
15 min	66.1	4.1	74.3	6.2	0.000
30 min	68.4	4.2	70.7	7.8	0.253
45 min	70.8	4.2	72.4	7.0	0.390
60 min	72.2	4.3	74.3	7.4	0.280
90 min	71.4	4.1	75.4	7.9	0.054
120 min	72.6	4.6	75.9	7.2	0.091

There was a statistically significant difference in mean DBP between 2 groups only at the initial period of the peri-operative period, with subjects in Bupivacaine group experiencing lesser diastolic blood pressure than subjects in the Ropivacaine group as suggested by the student "t" test and this difference wades off after 25 minutes from baseline injection.

Table 6: Comparison of mean arterial blood pressure (MAP) of the study groups at various peri-operative time points (n=30)

Peri-operative Mean arterial pressure	Group Bupivacaine (N=15)		Group Ropivacaine (N=15)		P value
	Mean MAP (mm Hg)	SD	Mean MAP (mm Hg)	SD	
0 min	90.3	7.9	97.9	6.1	0.002
15 min	81.7	4.8	86.1	4.7	0.007
30 min	83.9	4.6	84.4	6.0	0.769
45 min	86.1	4.4	86.3	4.5	0.888
60 min	87.7	4.4	89.7	5.1	0.194
90 min	87.9	4.2	90.0	5.3	0.174
120 min	89.0	4.5	91.0	5.1	0.207

There was a statistically significant difference in MAP between 2 groups both at the initial period (before 20 min) and towards the end (after 120 min) of the perioperative period, with subjects in Bupivacaine group experiencing lesser mean arterial pressure than subjects in the Ropivacaine group as suggested by the student "t" test.

Table 7: Comparison of blockade characteristics of the study sample (n=30)

Characteristics	Group Ropivacaine (N=15)		Group Bupivacaine (N=15)		P value
	Mean	SD	Mean	SD	
Onset of sensory and motor blockade (min)	5.4	2.1	4.9	2.2	0.426
Time to Peak block height(min)	8.9	2.7	8.7	3.1	0.870
Time for two Segments regression (min)	78.5	7.6	78.0	7.8	0.839
Time to motor blockade Bromage 3 (min)	7.4	1.7	6.0	2.4	0.039
Rescue analgesia (min)	148.7	9.2	183.4	6.6	0.000

The minor differences in the onset of sensory and motor blockade, time to Peak block height, time for two segments regression, time for regression and time for complete regression between the groups were not statistically significant ($p > 0.05$) and hence both the groups were comparable with regards to the above said parameters.

DISCUSSION

The aim of the study is to compare the postoperative analgesic efficacy using intrathecal 0.75% hyperbaric Ropivacaine with Fentanyl and intrathecal 0.5% hyperbaric Bupivacaine with Fentanyl for lower limb surgeries.

In our study, we compared the groups for postoperative analgesia using Numeric scoring system and the need of rescue analgesia after regression of sensory blockade, time of onset of sensory and motor blockade, time taken for peak block height, time taken to attain Modified Bromage score of 0 and postoperative complications were recorded.^[1]

The patients in both groups were compared with respect to age, sex, height, weight, ASA physical status.^[2]

The mean time for onset of sensory blockade and motor blockade in group B was 4.9 minutes and in group R was 5.4 minutes with p value of 0.426 which was statistically insignificant which was similar to Dr Lee et al study.^[3]

The mean time for peak block height in group B was 8.7 minutes and in group R was 8.9 minutes (p value – 0.870). This data showed that there is statistically insignificant between the two groups which was similar to Dr Kumkum Gupta study.^[4]

The mean time taken for two segment regression in group B is 78 minutes and in group 78.5 minutes with p value of 0.839 which was statistically insignificant.^[5]

The mean time for regression to L1 in group B was 78.5 minutes and in group R was 78 minutes with p value of 0.054 which was statistically insignificant. This was similar to Dr. Kumkum Gupta et al study.^[6]

The mean time for complete regression to S2 in group B was 140.8 minutes and in group R was 198 minutes with p value of 0.00. This data showed that there was statistically significant with p value of 0.00 which was similar to Dr KumKum Gupta et al study.^[7]

The mean time taken to attain Bromage score 0 in group B was 180.8 minutes and in group R was 130.8 minutes with p value of 0.00. This observation showed that Ropivacaine group had shorter duration

of motor blockade which was similar to Dr Lee et al study.^[8]

With respect to haemodynamic parameters, we observed that Ropivacaine group had stable hemodynamics compared to Bupivacaine group with p value of < 0.05 which was statistically significant. This was similar to Dr. Bhupendra Tiwari et al study.^[9]

The mean time taken for first rescue analgesia in group B and group R was 183.4 minutes and 148.7 minutes respectively. The p value of 0.00 which was statistically highly significant which was similar to Dr Sheetal Jagatap et al study.^[10]

From the above data observations, we observed that Bupivacaine provides prolonged duration of sensory and motor blockade. Ropivacaine provides early motor blockade with stable haemodynamics. No complications were observed in both groups.

CONCLUSION

In our study to compare the postoperative analgesia using intrathecal 0.75 % isobaric Ropivacaine with Fentanyl and intrathecal 0.5% hyperbaric Bupivacaine with Fentanyl, we conclude that 0.75 % hyperbaric Ropivacaine provides early recovery of sensory and motor blockade with stable haemodynamics.

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